REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on March 31, 2006. A petition for a one month extension of time is submitted herewith. The Director is authorized to charge $120.00 for the petition for one month extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112843-76 on the account statement.

Claims 1, 3-11 and 17-19 are pending in this application. Claim 2 was previously canceled. Claims 12-16 were previously withdrawn. In the Office Action, the specification is objected to, Claims 1, 3-11 and 19 are rejected under 35 U.S.C. §112, first paragraph, and Claims 17-18 are rejected under 35 U.S.C. §102. In response, Claims 17-18 have been amended. These amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, the specification is objected to. Specifically, the Patent Office alleges that in Fig. 2 the Western blot analysis of human milk fractions only shows the band of 130 kDa for various milk fractions containing OPG and does not show the bands of 80 and 200 kDa for these milk fractions or the band of 55 kDa for recombinant OPG. In the Office Action, Claims 1, 3-11 and 19 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Patent Office alleges that there is a lack of description for osteoprotegerin that includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa. Applicants respectfully submit that the objection to the specification and the rejection of Claims 1, 3-11 and 19 under 35 U.S.C. §112, first paragraph, are improper as discussed below.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. There is no *in haec verba* requirement. Claim limitations can be supported through express, implicit or inherent disclosure. See, MPEP 2163.

Applicants submit that Fig. 2 in the present application shows the results of an example of a Western Blot analysis performed by Applicants under the conditions as indicated. As understood by the skilled artisan, analytical experimental results using specific experimental conditions with the Western Blot analysis depend upon the chosen experimental conditions (e.g. agent used for revealing, gel conditions, etc.). One specific set of experimental conditions will provide good results for a particular protein, while possibly providing less clear results during the separating and revealing of another protein. As a result, it is commonly observed throughout the experimental work that a specific analytical experiment can reveal the presence of one compound clearly, while less clearly revealing the presence of another compound.

With respect to the Patent Office's assertion regarding bands allegedly lacking for a protein having 200 kDa, Applicants submit that a band, which is weaker in appearance but nevertheless clearly visible, is present in the region of about 200 kDa in Fig. 2. Consequently, the skilled artisan would conclude that the present inventors were at least in the possession of a protein characterized by the sequence as indicated and having a respective molecular weight of 130 and 200 kDa.

Moreover, it is well known to one having ordinary skill in the art that during a Western Blot analysis chemical reactions such as, for example, dimerisations and trimerisations may occur. Such chemical reactions could reasonably explain the absence of a band for recombinant OPG at 55 kDa and the presence of bands having a higher molecular weight. For example, OPG is well known to dimerize to a dimer of 110 kDa, for example when secreted extracellularly. See, specification, page 12, lines 11-13.

Because Fig. 2 illustrates that, under the experimental conditions chosen for this Western blot analysis (e.g. different from the conditions prevailing in milk) chemical reactions can occur giving rise to compounds of higher molecular weight, it can be reasonably concluded that the OPG of 80 kDa (i.e. the least glycosylated OPG) may have been subjected to the same chemical reactions that potentially occurred in the case of the recombinant OPG of 55 kDa. This could explain the weakness or absence of a band for OPG at 80 kDa. Nevertheless, the absence of such a clearly visible band for OPG at 80 kDa in the particular experiment does not mean it does not exist but reflects the routine variation using different experimental conditions encountered by Applicants when conceiving and reducing to practice the present invention.

Finally, Applicants respectfully submit that there is sufficient support in the specification that one skilled having ordinary skill in the art would reasonably conclude that the Applicants had possession of the claimed invention. For example, the specification states that the OPG of the present invention may be obtained from a milk source, derived from a mammal, in particular from human or bovine milk or colostrum. Human milk OPG has an amino acid sequence of 380 aa and exhibits a molecular weight of approximately 80, 130 and 200 kda when compared to protein markers which were used as molecular weight standards (e.g. BioRad). See, specification, page 7, line 29 to page 8, line 7. Applicants provide further details regarding the detected bands in the Western Blot Analysis example. See, specification, page 12, lines 10-13. Because these claimed elements are sufficiently described in the specification, one having ordinary skill in the art would understand that Applicants had possession of the claimed subject matter even without additional figures.

Based on at least these noted reasons, Applicants believe that Claims 1, 3-11 and 19 fully comply with 35 U.S.C. §112, first paragraph. Accordingly, Applicants respectfully request that the objection to the specification and the rejection under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claim 17 is rejected under 35 U.S.C. §102(b) as anticipated by Clinical and Experimental Immunology, 104, 543-546 (June 1996) to D'Ostilio et al. ("*D'Ostilio*") as evidenced by US 2004/0137074. Claim 18 is rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,015,938 to Boyle et al. ("*Boyle*"). Applicants respectfully disagree with and traverse these rejections for at least the reasons set forth below.

Applicants have amended Claim 17 to recite, in part, a food material containing an osteoprotegerin isolated from human or bovine milk or colostrum, wherein the osteoprotegerin has been added to the food material. The amendment is supported in the specification, for example, at page 3, lines 17-21 and page 5, lines 11-23. For example, the resulting claimed product is enriched with osteoprotegerin. In contrast to amended Claim 17, *D'Ostilio* fails to disclose or suggest a food material having osteoprotegerin added to it.

Applicants have amended Claim 18 to recite, in part, a method comprising adding to a food material, enteral composition or pharmaceutical composition an amount of osteoprotegerin isolated from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately

80, 130 and 200 kDa. The amendment is supported in the specification, for example, at page 3, lines 17-21 and page 5, lines 8-23. Contrary to amended Claim 18, *Boyle* fails to disclose or suggest an osteoprotegerin including a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa.

For the reasons discussed above, Applicants respectfully submit that Claims 17-18 are novel, nonobvious and distinguishable from the cited references. Accordingly, Applicants respectfully request that the rejections of Claims 17-18 under 35 U.S.C. §102 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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